



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------------|
| 10/522,377 | 01/26/2005 | Caroline Garey | P08555US00/BAS | 7987 |
| 881 7590 11/28/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314 | | | EXAMINER GABEL, GALENE | |
| | | | ART UNIT 1641 | PAPER NUMBER |
| | | | MAIL DATE 11/28/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,377

Applicant(s)

GAREY ET AL.

Examiner

GAIL R. GABEL

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and arguments filed April 14, 2008 is acknowledged and has been entered. Claims 1-15 have been amended. Claims 18 and 19 have been added. Accordingly, claims 1-15, 18, and 19 are pending and are under examination.

Withdrawn Rejections or Objections

2. All rejections / objections not reiterated herein, have been withdrawn.
3. In light of Applicant's amendments, the rejection of claims 1-15, 18, and 19 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.
4. In light of Applicant's amendments, the rejection of claims 1-15, 18, and 19 under 35 U.S.C. 102(b) as being anticipated by Dames (WO 00/16893), is hereby, withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-15, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bruchez et al. (US 2001/0034034 A1).

Bruchez et al. disclose systems for multiparameter analysis of analytes comprising insoluble microparticle primary supports (microspheres/beads) in variable sizes and spectrally encoded or barcoded with organic dye, having a primary analyte attached thereto. The system further comprises insoluble microparticle secondary supports which include therein identification means (Q-dots / labels) having secondary analytes attached thereto (Figure 1C and [0101, 0110-0111, 0134]). The primary and secondary supports have characteristic spectral emissions which result from varying particle size and size distribution [0020-0021]. The insoluble microparticle primary supports have varying dimensions of 10 μm and suspended in a fluid solution ([0078, 0156] and Example 12). The dimension of the primary support is less than 50 μm (less than 500 μm), the dimensions of which is about 10 μm [0302-0303]. The largest dimension of the secondary support is less than that of the primary support (1 nm to 1000 nm) [0074]. The system further includes a measuring means arranged in communication with the fluid solution for monitoring interaction between the primary analytes, targets, and the secondary analyte by detecting the identification means of the primary support and the secondary support attached thereto ([0112, 0126-0127, 0144, 0204], Example 3 and Example 4). The liquid suspension can be placed on a solid flat substrate which comprises a main surface extending substantially in a two-dimensional plane and has tertiary analytes fixedly arranged thereon for positional identification,

whereupon the tertiary analytes are capable of interacting with the at least one primary analyte (Figure 1A or 1B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over et al. (US 2001/0034034 A1) in view of Mandeck (US Patent 6,361,950).

Bruchez et al. are discussed supra. Bruchez et al. differ from the instant invention in failing to disclose that the identification means is a radio frequency identification transponder.

Mandecki discloses using solid supports having attached thereto probes or binding ligands for use in multiplexed assays, and wherein each one of the solid supports is further associated with a radio frequency identification transponder (RFID) so that data concerning the multiplexed assays are encoded into the transponders (Abstract and column 4, lines 47-60). Advantage of transponder scanner systems is that two units are not electrically connected by wire but are coupled inductively by use of electromagnetic radiation. Most importantly the narrow focus of beam of a laser light enable only one transponder to be active at a time during decoding step, hence, significantly reducing noise level (column 1 line 56 to column 2, line2 and column 6, lines 23-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute RFID as taught by Mandecki into the multiplexed analytical systems as taught by Bruchez as an identification means, because RFID scanner systems have the advantage of reducing noise levels when measuring specific interactions between probes and analytes, which can add accuracy into the multiparametric systems and method of detecting analytes as taught by Dames and Bruchez.

Response to Arguments

7. Applicant's arguments filed October 27, 2008 have been fully considered but they are not persuasive.

A) Applicant argues that the Bruchez reference does not anticipate the claimed invention because the Bruchez et al. does not disclose using a population of Qdots with different identities, i.e. emission wavelengths against a further population of Qdots that also have different identities. Applicant contends that Bruchez et al. only disclose use of spectrally distinct Qdot-conjugated antibodies reacting with antigens immobilized on microspheres.

In response, Applicant's argument is not on point because the rejection is on the basis of the Bruchez reference teaching a system that comprises insoluble microparticle primary supports (microspheres/beads) in variable sizes, spectrally encoded or barcoded with organic dye, i.e. identification means, and having a primary analyte attached thereto, and insoluble microparticle secondary supports which include therein identification means (Q-dots / labels) having secondary analytes attached thereto. Such embodiment is especially exemplified in Figure 1C, whereupon it is taught that the insoluble microparticle primary supports (microspheres/beads) in variable sizes are spectrally encoded or barcoded with organic dye as identification means having a primary analyte attached thereto, and the insoluble microparticle secondary supports are Q-dots having secondary analytes attached thereto. Accordingly, Bruchez et al. appears to clearly read on claim 1.

B) Applicant argues that the claimed invention discloses interacting two reacting analytes whereas the Bruchez reference only discloses at most use of multiplexing with respect to only one analyte.

In response, claim 15 appears to recite "arranging for measuring means to detect any binding interaction between one or more primary analytes and one or more secondary analytes by detecting the identification means..."; and therefore, does not exclude the disclosure of Bruchez et al. as embodied in Figure 1C. Specifically, claim 15 does not appear to exclude direct interaction between two interacting analytes as argued by Applicant that results to multiplexed interaction between two analytes.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIL R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

November 24, 2008